

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address AMVAC CHEMICAL CORPORATION 4695 MACARTHUR COURT, SUITE 1200 NEWPORT BEACH, CA 926601706		2. Case # and Name N/A - Topramezone Chemical # and Name: 123009 Topramezone				3. Date and Type of DCI and Number GENERIC ID # GDCI-123009-1578			
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.2100	Avian acute oral toxicity test (6)	N				C,Q,A	TGAI	12	
850.2300	Avian reproduction test (8)	N				C,Q,A	TGAI	24	
850.3040	Field testing for pollinators (2)	N				C,Q,A	TEP	24	
850.4500	Algal Toxicity (7)	N				C,Q,A	TEP	12	
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation (10)	N				C,Q,A	TGAI	12	
SS-1312	Honey bee larvae acute oral toxicity (9)	N				C,Q,A	TGAI	12	
SS-1313	Honey bee adult chronic oral toxicity (3)	Y				C,Q,A	TGAI	12	
SS-1314	Honey bee larvae chronic oral toxicity (4)	Y				C,Q,A	TGAI	12	
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.							11. Date <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div>		
Signature and Title of Company's Authorized Representative _____							13. Phone Number <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div>		
12. Name of Company <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div>									

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SS-1316	Field trial of residues in pollen and nectar (5)	Y				C,Q,A	TEP	24	
SS-1319	Semi-field testing for pollinators (tunnel or colony feeding studies) (1)	Y				C,Q,A	TEP	24	

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1. Company Name and Address BASF CORPORATION 26 DAVIS DRIVE, P.O. Box 13528 RESEARCH TRIANGLE PARK, NC 277093528		2. Case # and Name N/A - Topramezone Chemical # and Name: 123009 Topramezone				3. Date and Type of DCI and Number GENERIC ID # GDCI-123009-1578			
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.2100	Avian acute oral toxicity test (6)	N				C,Q,A	TGAI	12	
850.2300	Avian reproduction test (8)	N				C,Q,A	TGAI	24	
850.3040	Field testing for pollinators (2)	N				C,Q,A	TEP	24	
850.4500	Algal Toxicity (7)	N				C,Q,A	TEP	12	
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation (10)	N				C,Q,A	TGAI	12	
SS-1312	Honey bee larvae acute oral toxicity (9)	N				C,Q,A	TGAI	12	
SS-1313	Honey bee adult chronic oral toxicity (3)	Y				C,Q,A	TGAI	12	
SS-1314	Honey bee larvae chronic oral toxicity (4)	Y				C,Q,A	TGAI	12	
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			1	2	3				
SS-1316	Field trial of residues in pollen and nectar (5)	Y				C,Q,A	TEP	24	
SS-1319	Semi-field testing for pollinators (tunnel or colony feeding studies) (1)	Y				C,Q,A	TEP	24	

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: N/A - Topramezone

DCI Number: GDCI-123009-1578

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

Use Categories Key:

A - Terrestrial food crop

C - Terrestrial nonfood crop

Q - Residential outdoor use

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

- 1
 - a) The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based upon lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
 - b) Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (*Apis mellifera* L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)22&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en).
 - c) For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. *Bul OEPP/EPPO Bulletin* 22: 613-616.
 - d) A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.
- 2
 - a) The need for a field test for pollinators will be determined based upon lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
 - b) See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www2.epa.gov/sites/production/files/201406/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.
 - c) USEPA. 2012c. ¿Field Testing for Pollinators.¿ Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
 - d) A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.
- 3
 - a) OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees. *EFSA Journal* 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: <http://www.efsa.europa.eu/en/efsajournal/doc/3295>.
 - b) A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.
- 4
 - a) OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf

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- 5 b) A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.
- a) Measurements of residues in the pollen/nectar are needed based upon lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
- b) A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.
- o Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under.
 - o Consideration of the attractiveness of the selected crop to pollinators.
 - o Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time.
 - o Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators.
 - o Consideration of the market proportion of the selected target crop(s).
- 6 Only passerine species toxicity data are required.
- 7 Only navicula pelliculosa data are required.
- 8 Only data on mallard are required.
- 9 OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (*Apis mellifera*) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
- 10 ECM/ILV needed for soil. Only the ILV is needed for water.

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